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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,646	06/28/2005	Robert Nitsch	2958-131	1021
6449	7590	08/27/2007		
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 08/27/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/527,646

Applicant(s)

NITSCH ET AL.

Examiner

Iqbal H. Chowdhury, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,21 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

Claims 1-2, 21 and 30-33 are currently pending in the instant Office action.

In response to a previous Office action, a Final rejection (mailed on September 26, 2006), Applicants filed a response and amendment received on February 26, 2007, amending claims 1-2 is acknowledged. Claims 30-33 remain withdrawn and claims 3-20 and 22-29 remain cancelled. Claims 1-2 and 21 are under consideration and will be examined herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Advisory action. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/29/2007 has been entered.

Applicants' arguments filed on February 26, 2007, have been fully considered but are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Regarding rejoining of non-elected claims 30-33, applicants request for rejoinder is noted. However, current claims of elected Group claims 1-2 and 21 are not allowable at this time. When claims 1-2 and 21 would be allowable; rejoinder request would be evaluated at that

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time.

Claim Objection

Claim 1 is objected to as encompassing non-elected subject matter i.e. claim 1 continues to recite SEQ ID NO: 2-12, which are non-elected, (see Non-Final office action mailed on 3/24/2006). Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim 1 is indefinite and vague in the recitation of "neuronally active" which is ambiguous and confusing. It is unclear what does this phrase mean? What kind of activity is encompassed by this phrase? Accordingly, claims 2 and 21 are rejected, as they are dependent on claim 1.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claim 2 recites "said amino acid sequence" which is unclear as to the scope of sequences recited in claim 1. What does this refer to? Is "said amino

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acid sequence" referring to SEQ ID NOs: 1-12 or to any amino acid sequence having 95% identity to SEQ ID NO: 1-12?

New-Claim Rejections - 35 U.S.C. § 112(1)

Claims 1-2 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to an isolated protein having 95% identity to SEQ ID NO: 1. The specification does not contain any disclosure of the function of said protein except the statement as "neuronally active", which cannot be a specific function, as well as all the protein sequences that are 95% identical to SEQ ID NO: 1. The genus of above protein molecules is a large variable genus with the potentiality of having many different structures as well as having many different unknown functions. Therefore, many functionally unrelated proteins or peptides are encompassed within the scope of these claims. The specification discloses only several species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within

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the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Maintained-Claim Rejections - 35 USC § 112(1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of claims 1-2 and 21 under 35 U.S.C. § 112, first paragraph, as failing to comply with enablement requirement, is maintained. This rejection has been described in length in previous Office Actions. Applicant's amendments and lengthy arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that Applicants have amended claim 1 and further state that the claims, as amended, are fully enabled by the specification and that the amendments overcome all of the Examiner's remaining concerns. Applicants also argue that with respect to the recited

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mutations of the proteins with at least about 95% sequence identity to SEQ ID NOS. 1, the techniques to generate such mutant proteins are well known to the ordinarily skilled artisan, and thus, practicing the invention as now claimed would not involve undue experimentation.

This is not found persuasive because the enablement problem here is "how to use" the mutants and variants encompassed by 5% variation of SEQ ID NO: 1, while a skill artisan could make any protein with 95% identity to SEQ ID NO: 1, not all such variants can be used in the claimed method, and not all variants will have the desired activity and furthermore, the claim is not limited to these variants with activity.

As mentioned in the previous office action, Claim 1 and 2 are so broad as to encompass any neuronally active protein of SEQ ID NO: 1, which is 95% identical to SEQ ID NO: 1 or any protein which comprises at least one fragment having one N-terminal, C-terminal and/or internal deletion of the SEQ ID NO: 1 without any structural feature of said fragments. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins and fragments broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can

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be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and encoded amino acid sequence of only several proteins.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications including deletions at N-terminal, C-terminal and/or internal of a protein sequence, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable and the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has **not** been provided in the instant specification.

The specification does not support the broad scope of the claims which encompass any neuronally active protein of SEQ ID

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NO: 1, which is 95% identical to SEQ ID NO: 1 or which comprises at least one fragment having one N-terminal, C-terminal and/or internal deletion of the SEQ ID NO: 1 because the specification does not establish: (A) regions of the protein structure which may be modified without affecting its unknown activity; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying said polypeptide amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Therefore, the rejection is maintained.

Conclusion

Claims 1-2, 21 and 30-33 are currently pending.

Claims 30-33 are withdrawn.

Claims 1-2, and 21 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy

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can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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